Remarks

Claims 33-44 were pending in this application.

Claims 33, 39 and 42-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen et al. U.S. 5,860,957 in view of Palasis U.S. 6,689,103. Claims 33, 39 and 42-44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann et al. U.S. 6,551,276 in view of Palasis U.S. 6,689,103. Claims 34-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobsen et al. U.S. 5,860,957 or Mann et al. U.S. 6,551,276, as modified above, in view of Garstein et al. U.S. 6,379,324 and further in view of Saadat U.S. 5,899,915. These rejections are respectfully traversed for the reasons that follow.

Claim 33 has been amended to include the limitations of claim 34 and further limitations regarding the unique microneedle structure of the present invention. The limitation "curved surface" is supported in the specification on page 11, lines 8-23 and FIGS. 3A-5, 7I, 7J clearly show that the curved surface is "concave." More particularly, the examiner's attention is drawn to page 11, lines 12-14: "As noted above, isotropic etching is characterized by forming rounded surfaces, such as curved surface 70, as opposed to the more angular surfaces formed in anisotropic etching." (emphasis added) Claim 34 has been canceled since its limitations are now incorporated into claim 33.

Jacobsen et al. disclose an electronically controlled drug delivery system wherein a drug delivery device is strapped to the patient's arm or leg. However, Jacobsen discloses a conventional hypodermic needle, liquid jet nozzle, ionophorectic transdermal patch, and passive transdermal patch as means for delivering a drug to the patient. The focus of the invention is the provision of multiple pathways or means for delivering medication to the patient through the delivery device strapped to them.

Mann et al. disclose an electronically controlled drug delivery system that comprises an external infusion device and a remote commander. The external infusion device uses a conventional reservoir and tube set rather than microneedles to deliver the fluid to the patient.

Palasis discloses a fluid delivery system comprising an injection catheter that uses an array comprising a plurality of long slender "microneedles", each with an outside diameter of 0.005 to 0.05 inch and minimum length/width ratio of 10:1, on its distal end to deliver fluid to

the tissue of the heart or another organ. This distributes the fluid over a larger area of tissue than a single needle would. Some of the figures show a straight beveled end on the microneedles, but no explanation or further description is provided.

Garstein et al. disclose an intracutaneous microneedle array apparatus, which can be constructed using MEMS technology. FIG. 22 of Garstein et al. illustrates an array of cylindrically shaped microneedles and Gartstein further indicates that other shapes could be used. For example, FIGS. 23 and 25 disclose purely conical hollow microneedles with straight angled side surfaces and blunt annular tips. However, Gartstein et al. lack teaching of the microneedle having a beveled and non-coring tip.

The examiner tries to rely on FIG. 11A of Saadat for teaching a beveled non-coring tip on a relatively large tube or needle. However, there is nothing in Palasis, Saadat or Garstein et al. that suggests to one of ordinary skill in the microneedle art how to put such a beveled non-coring tip on a microneedle. While Saadat may arguably supply a suggestion or motivation to bevel a tube tip, there is no enabling disclosure by Saadat, Garstein, or Palasis on how to economically and practically achieve this structure in a microneedle. As discussed in the background of the invention section of the present application, this is an important unmet need that applicant's invention resolves.

Furthermore, none of these references shows or suggests the curved surface adjacent the beveled, non-coring tip. Thus, the combinations suggested by the Examiner would still not result in the claimed invention. Applicant's claw-like structure provides a strong microneedle that is both highly resistant to breakage and pierces the skin easily. The structure pierces the skin easily like a slender long cylindrical microneedle, but is not as susceptible to breakage. The structure has higher strength or breakage resistance like a purely conical microneedle, but requires less insertion force and thereby produces less trauma to the tissue due to the beveled tip and curved surface adjacent to the tip.

Claim 36 has been amended to depend from claim 33, but is believed to be patentable in its own right because the prior art fails to unambiguously teach that the height of the microneedle should be "substantially less than a width of said broad base." In fact, column 13, lines 28-62 of Garstein et al. suggest a height L32 of 50-200 microns and a base D35 of approximately 20 microns. See FIG. 17. By contrast, the applicant's short height and wide base claw-like structure

provides a strong microneedle that is both highly resistant to breakage and pierces the skin easily.

Claim 35 has been amended to depend from claim 36. Claim 37 has been canceled without prejudice.

Claims 38, 40 and 41 were objected to as being based upon a rejected base claim, but were deemed to be allowable if rewritten in independent form. Therefore, claim 38 has been rewritten in independent form. Claims 40 and 41 depend from claim 38 and at least derive their patentability therefrom. The preamble of claim 41 has also been amended to correctly recite a "drug delivery system" rather than a "diagnostic system" to be more consistent with the preceding claims. No new matter has been added in the correction of this error.

Claims 39 and 42-44 have been amended to depend from allowable claim 38 rather than claim 33. New claims 45-48 are similar to original claims 34-37 but depend from allowable claim 38. Thus, claims 38-48 should be in allowable form.

No fees or requests for extension of time are believed to be due in connection with this paper. However, please consider this a request for any other extension required and charge Deposit Account No. 50-3118 for any additional fees required.

Reconsideration and allowance of the claims of this application is respectfully requested.

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Respectfully submitted,
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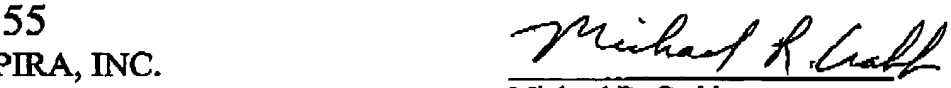

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